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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,265	04/22/2005	Michael B. Mathews	UMD-0092	1905
46046	7590	11/09/2006	EXAMINER	
LICATA & TYRRELL P.C. 66 EAST MAIN STREET MARLTON, NJ 08053			KINSEY, NICOLE	
			ART UNIT	PAPER NUMBER
			1648	
DATE MAILED: 11/09/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/505,265

Applicant(s)

MATHEWS ET AL.

Examiner

Nicole E. Kinsey, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-19 is/are pending in the application.
- 4a) Of the above claim(s) 7-12, 14 and 17-19 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4-6, 13 and 15 is/are ~~allowed~~ *allowable*. <sup>11/26</sup>
- 6) ☒ Claim(s) 16 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/6/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

Applicants' election with traverse of Group I (claims 1-6, 13, 15 and 16) in the reply filed on September 15, 2006 is acknowledged. The traversal is on the ground(s) that the claimed Tat protein is distinct from the Tat proteins of the prior art because of the presence of an asparagine at position 23 and the C-terminal amino acid sequence NCYCKKCCFHCQVCFITKALGISYGRKKRRQRRRAHQNSQTHQASLSKQ. This is not found persuasive.

The lack of unity dated September 8, 2006 is based on the claims as originally filed, not the currently amended claims. The special technical feature of Group I is a variant of HIV-1 Tat which exhibits higher transcriptional activation and stronger p-TEFb binding than wild-type HIV-1 Tat. A T23N (threonine to asparagine at position 23) amino acid change in wild-type HIV-1 Tat results in the claimed Tat protein with the above characteristics. This special technical feature does not make a contribution over the prior art as noted in Roof et al. and Starchich et al. (NCBI Accession Number P05908). Roof et al. discloses Tat-C, which has an asparagine at position 23. The Tat-C of Roof et al. has higher LTR activation than Tat-B, which does not have the T23N change. Starchich et al. discloses the sequence of a Tat protein with the T23N amino acid change. Therefore, unity of invention is lacking.

The requirement is still deemed proper and is therefore made FINAL.

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### ***Status of the Claims***

Claims 2-3 have been cancelled. Claims 7-12, 14 and 17-19 have been withdrawn from consideration, and claims 1-6, 13, 15 and 16 are under examination.

### ***Specification***

Applicants are required to state the priority claim in the first paragraph of the specification. The following paragraph is suggested.

This application is a 35 U.S.C. 371 filing of PCT/EP99/06623, filed 8 September 1999, which claims priority to U.S. Provisional Application 60/358,595, filed February 21, 2002.

Appropriate correction is required.

### ***Claim Objections***

Claim 1 is objected to for failing to clearly refer to the claimed subject matter: a protein. Claim 1 recites, "A variant of wild-type HIV-1 Tat protein". Suggested language is, "An isolated variant protein of wild-type HIV-1 Tat protein". Correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is drawn to a defective HIV virus comprising the Tat variant of claim 1 and a simian/human chimera virus. This wording is confusing. As written, it appears that the defective HIV virus contains a Tat variant and another virus (the simian/human chimera virus). Thus, there are two virus genomes present (the HIV virus as well as the simian/human chimera virus). If this is not the meaning intended, then applicants are required to amend the claim to clearly reflect the content of the defective HIV virus.

In addition, it is not clear what applicants mean by "defective." Is the HIV virus replication defective or is the virus defective because it contains the Tat variant? Is there a non-Tat mutant/defective protein present, but the virus can still integrate and replicate normally? Lacking a definition for the term "defective", the metes and bounds of the claim cannot be determined. Correction is required.

Claims 1, 4-6, 13, 15 and 16 are free of the prior art.

It is noted that the provisional application (60/358,595) teaches the introduction of a T23N change (threonine to asparagine at position 23) in wild-type HIV-I (strain IIXB), while the instant specification teaches the introduction of a T23N change in wild-type HIV-I (strain NL4-3).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Nicole E Kinsey, Ph.D.  
Examiner  
Art Unit 1648

*Stacy B. Chen 11/7/08*  
STACY B. CHEN  
PRIMARY EXAMINER